WISCONSIN DIVISION OF PUBLIC HEALTH
Department of Health and Family Services

TB Fact Sheet Series
for health care professionals

QUANTIFERON®-TB BLOOD TEST FOR TB INFECTION

The QuantiFERON®-TB test is an *in-vitro* diagnostic test intended to aid in the detection of infection with *Mycobacterium tuberculosis.*

Description of the test: The QuantiFERON®-TB assay detects cell mediated immune (CMI) responses to tuberculosis **infection** by measuring interferon-γ (IFN-γ) produced in whole blood after incubation with tuberculin purified protein derivative (PPD). The immune response to infection with *Mycobacterium tuberculosis* is predominantly a CMI response and results in sensitization of T-cell lymphocytes specific to *M. tuberculosis* antigens, which circulate in the blood. IFN-γ is a protein produced by sensitized T-cells upon stimulation with their specific antigen.

The QuantiFERON®-TB test is intended for use only with blood specimens collected into heparin, and blood samples must be incubated with tuberculin **within 12 hours** of collection. Results from the test can be obtained within 24 hours.

Intended use and Suitable Populations: The QuantiFERON®-TB test should not be the sole basis for determining TB infection and results must be interpreted with all other clinical and historical patient data to determine the risk of TB infection. A negative QuantiFERON®-TB result alone does not exclude the possibility of TB infection.

The QuantiFERON®-TB test has been evaluated for use with immunocompetent, healthy adults with and without identified risk factors for latent TB infection (LTBI). QuantiFERON®-TB has also been evaluated in individuals with culture-proven TB disease. The test has **not** been evaluated for use with children, infants, adolescents (<17 years), pregnant women, immunocompromised individuals (including HIV positive individuals), or people with clinical conditions predisposing immunosuppression (i.e. diabetes, silicosis, cancers, organ transplants), or those taking immunosuppresive medication.

Care should be taken when interpreting QuantiFERON®-TB results in individuals who have received a tuberculin skin test (TST or Mantoux) within the last 12 months as QuantiFERON®-TB results may be boosted or falsely positive following prior skin testing. The effects of the TST on subsequent QuantiFERON®-TB results has not been evaluated.

Interpretation of Results: In the QuantiFERON®-TB test, responsiveness to *M. tuberculosis* tuberculin is expressed as a percentage of the individual's response to a non-specific mitogen stimulus (percent Human Response). This allows for variations between the ability of different blood samples to produce IFN-γ. In a small number of cases, individuals may fail to respond to the mitogen stimulation and the test result is recorded as "Indeterminate."

Two different percent Human Response value cut-offs, based on the individual's risk factors for *M. tuberculosis* exposure, are used.

- >15% Human response indicates a **likelihood** of TB infection for individuals with a recognized risk factor for TB exposure.[2]
- >30% Human response indicates a **likelihood** of TB infection in individuals with no identified risk factors for TB exposure.

QuantiFERON®-TB also measures IFN-γ produced in response to PPD from *Mycobacterium avium* as a control. A second test cut-off (percent Avian Difference) is used to determine if the individual's response is predominantly directed towards the *M. avium* PPD and the individual is **unlikely** to be *M. tuberculosis* infected.

The laboratory will report 1 of 4 results. These reports and their interpretation are outlined in the chart below.

Report	Interpretation
QuantiFERON®-TB ≥ 30%	MTB infection likely.
QuantiFERON®-TB 15-30%	1. MTB infection not likely for low risk individuals. 2. MTB infection likely if risk identified.
QuantiFERON®-TB <15% or not significant	MTB infection NOT likely.
QuantiFERON®-TB INDETERMINATE	Result not obtained.

For more information about QuantiFERON®-TB, call the TB Program at (608) 266-9692.

REFERENCES AND NOTES

[1]Cellestis Limited. http://www.cellestis.com

[2]American Thoracic Society. Diagnostic standards and classification of tuberculosis. Am J Respir Crit Care Med, 2000;161:1376-1395.

[3]Mazurek, etal. Comparison of a whole-blood Interferon γ assay with tuberculin skin testing for detecting latent Mycobacterium tuberculosis infection. JAMA. 2001;286(14): 1740-1747.

[4]Centers for Disease Control and Prevention. Guidelines for Using the QuantiFERON ® -TB Test for Diagnosing Latent Mycobacterium tuberculosis Infection. MMWR 2003:52(No. RR-2):15-18.